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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,212	12/04/2001	Jeong S. Lee	ACSC 60308 (2864)	7883

7590 06/16/2004

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EXAMINER	
DESANTO, MATTHEW F	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,212	LEE ET AL.	
	Examiner	Art Unit	
	Matthew F DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *6-15,20,22,34 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,16,17,23-33,35 and 37-45* is/are rejected.

7)☒ Claim(s) *18,19 and 21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: PEEK RESIN PROPERTIES and Reference: Polymer Properties.

DETAILED ACTION

Election/Restrictions

1. This application contains claims 6-15, 20, 22, 34, 36, are drawn to an invention nonelected. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

2. Claim 40 is objected to because of the following informalities: there seems to be a typographical error. Appropriate correction is required.

Claim Rejections –

35 USC § 102 or 35 USC § 103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-5, 9, 16, 17, 25, 27 – 33, and 37-45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Estrada et al. (USPN 6193686).

Estrada et al. discloses a balloon (15) catheter with an elongated shaft having an inflation lumen, a guide-wire receiving lumen, a proximal shaft section comprising a proximal tubular member, a distal shaft section comprising an outer tubular member, and an inner tubular member and a reinforcing member (27) formed of a first polymeric (PEEK) material having a glass transition temperature greater than the glass transition temperature of a second polymeric material (Nylon 12) forming the distal portion of the proximal tubular member. (Figures 1 – 11, Column 5, lines 8-45, and entire reference).

The examiner read through the specification and found the chemical compounds that makeup the reinforcing member and the proximal tubular member of the prior art and then looked up there glass transition temperatures on the internet. The examiner found the temperatures on the following two websites:

http://www.zeusinc.com/peek_resin.asp (for nylon) and

www.sigmaaldrich.com/img/assets/3900/Thermal_Transitions_of_Homopolymers .pdf – (for PEEK).

After reviewing the websites it is inherent that the PEEK will have a higher glass transition temperature then nylon and thus forming the basis for the rejection on this patent application.

6. Claims 1-5, 9, 16, 17, 25, 27 – 33, and 37-45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Happ et al. (USPN 6575958).

Happ et al. discloses a balloon (22) catheter with an elongated shaft having an inflation lumen, a guide-wire receiving lumen, a proximal shaft section comprising a proximal tubular member, a distal shaft section comprising an outer tubular member, and an inner tubular member and a reinforcing member (130) formed of a first polymeric material (col. 5, lines 49-68) having a glass transition temperature greater than the glass transition temperature of a second polymeric material (Nylon 12) forming the distal portion of the proximal tubular member. (Figures 1 – 19, Column 4, line 65 – Column 5, line 4, and entire reference).

The examiner read through the specification and found the chemical compounds that makeup the reinforcing member and the proximal tubular member of the prior art and then looked up there glass transition temperatures on the internet and the temperatures on the following two websites:

http://www.zeusinc.com/peek_resin.asp (for nylon) and

www.sigmaaldrich.com/img/assets/3900/Thermal_Transitions_of_Homopolymers .pdf – (for PEEK).

After reviewing the websites it is inherent that the PEEK (reinforcing member) will have a higher glass transition temperature then nylon (proximal tubular member) and thus forming the basis for the rejection on this application.

Claim Rejections - 35 USC § 103

7. Claims 1-5, 9, 23-33, 35, and 37-39, 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verbeek (USPN 5690613), and further in view of Rau et al. (USPN 6024722) and in view of Samuelson et al. (USPN 6,165,166).

Verbeek discloses a balloon (35) catheter with an elongated shaft having an inflation lumen, a guide-wire receiving lumen, a proximal shaft section comprising a proximal tubular member (50) with a mandrel (30), a distal shaft section comprising an outer tubular member (80), and an inner tubular member (70) and a reinforcing member (13,17) formed of a first polymeric material polymeric reinforcing member around or within the proximal portion of the inner tubular member or the distal portion of the proximal tubular member, wherein a second polymeric material is used to form the distal portion of the proximal tubular member, as well as having a mandrel within the inflation lumen. (Figures 1A, 1B, 1C, and entire reference), but the reference fails to disclose the polymeric reinforcing member is formed from a thermoset or thermoplastic polyimide, and wherein the second polymeric material is formed from a nylon or polyether block amide, polyurethane, and adhesive polymer and wherein the first polymeric material has a higher glass transition temperature then the second polymeric material.

Rau et al. discloses the use of thermoplastics and thermoset polyimide in balloon catheters because of the high strength and flexibility. (Column 1, line 32-45, and entire reference)

Samuelson et al. discloses a catheter with different layers and each layer has a different glass transition temperature, and wherein the outer layer has the greatest glass transition temperature, as compared to the inner most layer, which has the lowest glass transition temperature. The invention discloses that varying the glass transition temperature provides many advantages. (Column 4, lines 7-37).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the teachings of Verbeek with the teachings of Rau et al. and Samuelson et el. because Rau et al. discloses the advantage of using a thermoset polyimide in a catheter wall because of the high strength and flexibility and Samuelson et al. disclosed using different polymers with different glass transition temperatures.

Allowable Subject Matter

8. Claims 18, 19 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The indicated allowability of claim 41 is withdrawn.

10. The examiner would like to note that if the subject matter of claims 18, 19 or 21 is incorporated into any independent claim that exists, it should put the claim in allowable form.

Response to Arguments

11. Applicant's arguments with respect to all the claims have been considered but are not persuasive.

12. With regards to the 103 Rejection the applicant does not show any support or show any lack of teachings and therefore the examiner holds the rejection.

13. With regards to claim 29, the term "about" is a broad term and gives the measurements a range from what is being claimed; therefore the examiner determines that the range of the reference (Happ et al.) would fall in the range claimed. If the applicant deletes the term about, the examiner would withdraw the rejection based on that claim.

The examiner is showing this links in support of his rejection, because they show the glass transition temperature and further support the rejection.

This link shows the glass transition temperature of Nylon.

http://www.zeusinc.com/peek_resin.asp

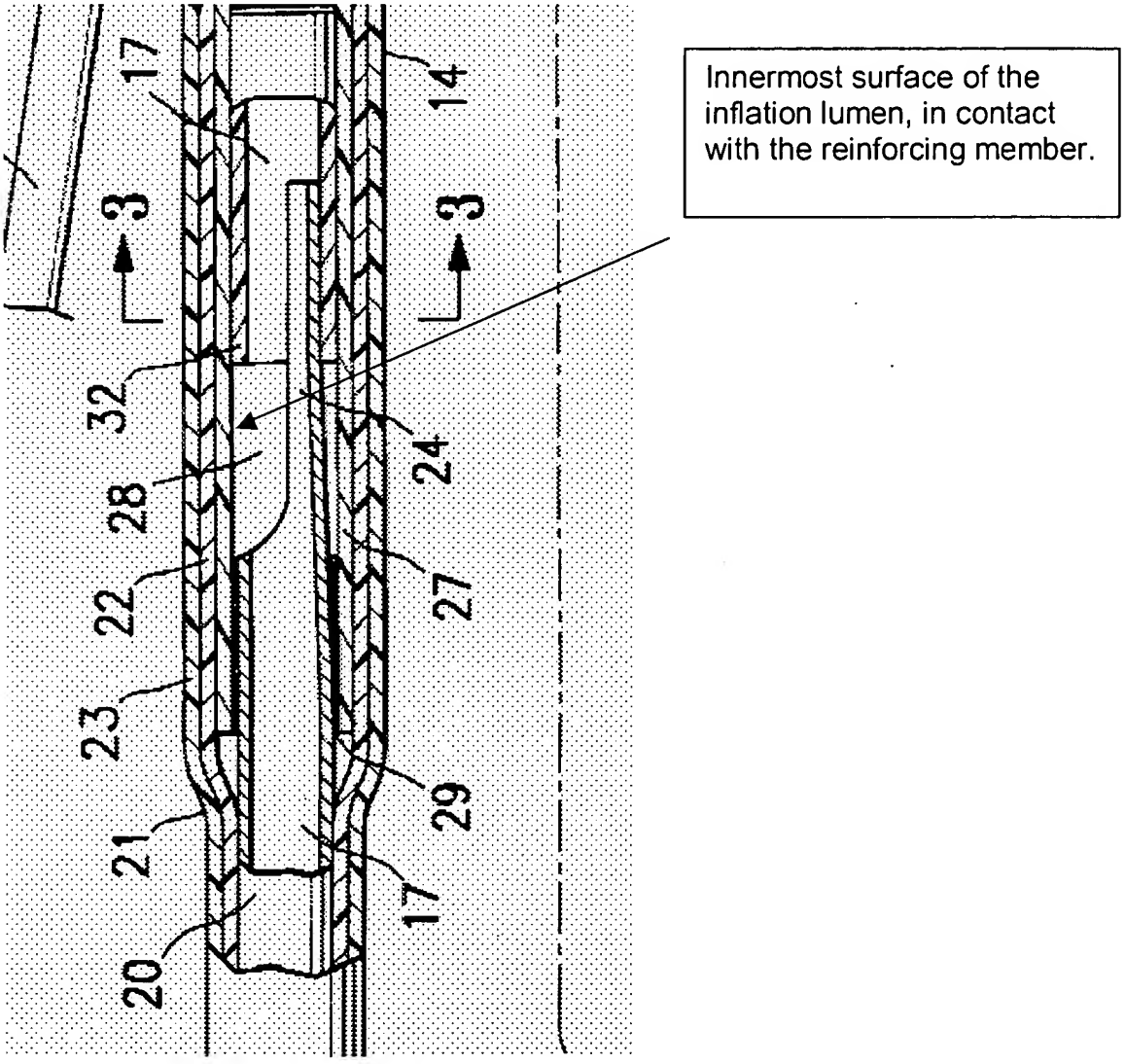
This link shows the glass transition temperature of PEEK.

www.sigmaaldrich.com/img/assets/ 3900/Thermal_Transitions_of_Homopolymers.pdf –

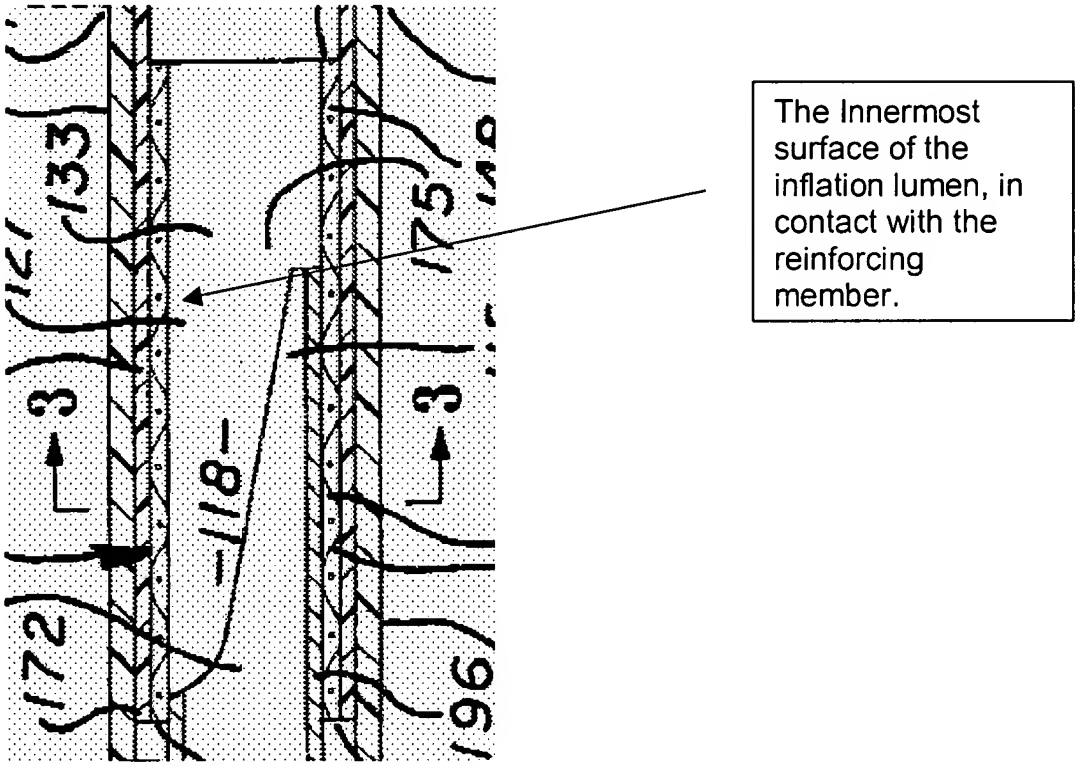
The above links show that nylon (the second polymeric material) has a low glass transition temperature then PEEK (the first polymeric material of the reinforcing member).

The examiner would like to note that each chemical compound such as Nylon has multiple variations or resins and that each different variation or resin has different properties and therefore could have different glass temperatures.

With regards to the Estrada et al. not showing an innermost surface of the shaft extending along the inflation lumen, is not true and the examiner disagrees. See Figure below.



The examiner also disagrees with the applicant with regards to Happ et al. The examiner has submitted support for the rejection with respect to the glass transition temperature. The examiner further disagrees with the view that does not define an innermost surface of the reinforce member in contact with the inflation lumen. See figure below.



Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Art Unit 3763
June 10, 2004

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
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